5. 510(k) Summary

SUMMARY

Submitter's name: Address:	Vidacare Corporation 4350 Lockhill Selma Road Shavano Park, TX 78249-2095
Phone: Fax number:	210-375-8500 210-375-8537
Name of contact person:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 Fax: 949-552-2821
Date the summary was revised:	October 12, 2011
Name of the device:	The OnControl Bone Access System by Vidacare®
Trade or proprietary name	The OnControl Bone Access System by Vidacare®
Common or usual name	Cement Dispenser Conduit for Vertebroplasty and Bone Biopsy Needle
Classification Panel	Orthopedic Spine Devices Branch

Product Code	Classification Regulation	Classification Name
OAR	888.4200	Injector, vertebroplasty
MOQ	878.4820	Battery, replacement, rechargeable
KNW	876.1075	Instrument, biopsy

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K081713	Vertebral Access System by Vidacare®	Vidacare Corp
2	K022169	Clearview Plus Bone and Vertebral Body Biopsy Needles	Parallax Medical

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Description of the device:

The OnControl Bone Access System by Vidacare® consists of a reusable Power Driver and a disposable sterile needle set in a sealed tray. The sealed tray contains 1 coupler with driver sterile sleeve, 1 beveled needle set and 2 sharps protectors. The Vertebral (Access and) Biopsy Needle Set is an 11 gauge, 152 mm cannula made of 304 stainless steel, with beveled cutting tip and stylet. The biopsy and vertebroplasty needle are the same needle. The needle sets are identical in gauge, length and materials to the predicate devices: the Vertebral Access System (cleared via K081713) and 11g, the same as Clearview Plus Bone and Vertebral Body Biopsy Needles (cleared via K022169). The powered driver is identical to the predicate driver cleared via K081713.

Under fluoroscopic imaging guidance, activation of the driver assists the clinician to insert the vertebral needle set through the cortex of the bone, into the vertebral body. The driver is then separated from the hub of the needle set by retracting the OnControl Connector release mechanism ring on the OnControl Connector. The needle set consists of two parts, an 11g outer cannula (3.05mm x 197mm) with an inner stylet (diameter of 2.54mm). The inner stylet is used only to penetrate the cortex and is then removed. A standard Luer lock (part of the 11 gauge cannula) permits attachment of the syringe for aspiration. The driver is activated and advanced to obtain the biopsy specimen and then withdrawn.

The driver is then separated from the needle assembly for specimen removal.

Indications:

The OnControl Bone Access System by Vidacare® is intended for use with a standard cement delivery system for the fixation of fractures of the vertebral body using vertebroplasty and for bone biopsy. This system does not contain cement.

Summary of the technological characteristics of our device compared to the predicate devices:

The predicates and the Vidacare Vertebral Biopsy System were compared in the following areas and found to have similar technological characteristics and to be equivalent.

Indications for Use
Target Population
Driver Design Features
Needle Design

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Technique
Sterility
Biocompatibility
Anatomical Sites

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 0 2011

Vidacare Corporation
% Regulatory Specialists, Inc.
Ms. Grace Holland
3722 Ave. Sausalito
Irvine, California 92606

Re: K112468
Trade/Device Name: The OnControl Bone Access System by Vidacare®
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW, OAR
Dated: October 12, 2011
Received: October 18, 2011

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

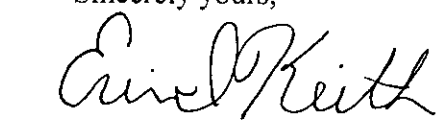
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K112468

Device Name: The OnControl Bone Access System by Vidacare®

Indications for Use:

The OnControl Bone Access System by Vidacare® is intended for use with a standard cement delivery system for the fixation of fractures of the vertebral body using vertebroplasty and for bone biopsy. This system does not contain cement.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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